PENTASA® 1g Prolonged Release Tablet
PENTASA® 500 mg Prolonged Release Tablets

FERRING PHARMACEUTICALS

For use in adults and children from the age of 6 years.

Active ingredient: Mesalazine.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PENTASA® prolonged release tablets are and what they are used for

PENTASA® prolonged release tablets are an intestinal therapeutic agent.
PENTASA® prolonged release tablets are used in:
- Acute treatment of ulcerative colitis (inflammation of the large intestine with ulceration) and prophylaxis for relapse.
- Treatment for symptomatic improvement in cases of active Crohn's disease.

2. What you need to know before you take PENTASA® prolonged release tablets

Do not take PENTASA® prolonged release tablets
- If you are allergic to Mesalazine, salicylic acid or its derivatives (e.g. acetylsalicylic acid) or to any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver and renal function impairment.

Warnings and precautions
Talk to your doctor or pharmacist before taking PENTASA® prolonged release tablets.
Tell your doctor before using PENTASA® prolonged release tablets
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Take special care with this medicine:
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4;
- if you are allergic to **sulphasalazine** (risk of allergy to salicylates);
- if you currently have or have previously had liver and/or **kidney disease**;
- if you have a medical condition that can make you prone to **bleeding**;
- if you have an active **peptic ulcer** (stomach ulcer or duodenal ulcer);
- if you are on **medication** that may affect **kidney function** e.g. non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid;
- if you have lung diseases, in particular asthma;
- If you suddenly develop abdominal cramps, abdominal pain, fever, severe headache and rash. In such circumstances you should stop taking PENTASA® immediately;
- Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

While you are on treatment with this medicine, your doctor will normally arrange blood tests to check your kidney function especially at the beginning of treatment.

Other medicines and PENTASA® prolonged release tablets
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. This is especially important if you are taking any of the following:
- **Azathioprine** (used after transplantations or to treat auto-immune diseases);
- **6-mercaptopurine or thioguanine** (chemotherapy, used to treat leukaemia);
- Certain agents that inhibit blood clotting (medicines for thrombosis or to thin your blood).

In patients with a known hypersensitivity to sulphasalazine, treatment with PENTASA® prolonged release tablets should only be commenced under careful medical supervision.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There is limited experience with the use of Mesalazine during pregnancy and breast-feeding.

Pregnancy
PENTASA® prolonged release tablets should not be used during pregnancy, except when the potential benefits of the treatment outweigh the possible hazards in the opinion of the doctor.

Breast-feeding
Blood disorders have been reported in new-borns of mothers being treated with this medicine. The new-born may develop allergic reactions after breast-feeding, e.g. diarrhoea. Your doctor has to decide if breast-feeding is to be interrupted or if treatment with PENTASA® prolonged release tablets should be given up. In doing so, the benefit of breast-feeding for the infant as well as the benefit of therapy for the woman has to be considered.

Driving and using machines
PENTASA® prolonged release tablets have no effect on the ability to drive and use machines.

Note: The risk of colorectal cancer (CRC) is slightly increased in ulcerative colitis, observed effects of mesalazine in experimental models and patient biopsies support the role of mesalazine in prevention of colitis-associated CRC, with downregulation of both inflammation dependent and non-inflammation dependent signalling pathways involved in the development of colitis-associated CRC.

3. How to take PENTASA® prolonged release tablets

Always take PENTASA® prolonged release tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is:

Adult:
For treatment of acute ulcerative colitis, your doctor will prescribe up to 4 g mesalazine per day, divided in single doses. You may take up to 2 PENTASA® 1g prolonged release tablets twice a day, or up to 4 PENTASA® 500mg prolonged release tablets twice a day.

For prophylaxis of further inflammatory episodes, your doctor will usually prescribe 1.5 g mesalazine per day, e.g. 3 times a day 1 PENTASA® 500 mg prolonged release tablet.

For treatment of acute Crohn's disease, your doctor will prescribe up to 4 g mesalazine per day, divided into 2 – 3 single doses, e.g. twice a day 1 - 2 PENTASA® 1g prolonged release tablets each or 2 – 4 PENTASA® 500mg prolonged release tablets each. or 3 times a day 2 – 3 PENTASA® 500 mg prolonged release tablets each (30-50 mg/kg body weight/day).

Children from the age of 6 years:
Ulcerative colitis (acute treatment and prophylaxis of acute ulcerative colitis) and Crohn's disease (acute treatment):
The dose given to children is up to the discretion of the physician and depends on the body weight. It is usually recommended that children with a body weight of up to 40 kg should receive half the dose given to adults and children with a body weight above 40 kg should receive the normal adult dose.

Method of administration:
Take the PENTASA® prolonged release tablets without chewing, preferably between meals, with sufficient fluid or put them into water or fruit juice, stir and drink.

Duration of administration:
The duration of administration is up to the discretion of the treating physician. It depends on the course of the disease. PENTASA® prolonged release tablets are suitable for long-term use.

Note:
The tablets consist of numerous microcapsules and thus seem to have grey specks. This pattern is normal. The covers of the microcapsules are excreted undigested. These covers may be visible in the faeces as white pin-size particles.

If you feel that the effect of PENTASA® prolonged release tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more PENTASA® prolonged release tablets than you should:
In the event of overdose, contact your doctor or nearest casualty department immediately.

If you forget to take PENTASA® prolonged release tablets:
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effets

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There have been very few reports of a severe allergic reaction (including severe skin erosions that may affect the skin as the protective barrier of the body). The allergic reaction might lead to swelling of the face and neck and/or difficulty in breathing or swallowing (Quincke´s oedema). If this happens contact your doctor or nearest casualty department immediately.

Stop using PENTASA® prolonged release tablets and seek medical attention immediately if you notice any of the following symptoms:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms.

The most frequent side effects seen in clinical trials are diarrhea, nausea, abdominal pain, headache, vomiting and rash.

Occasionally, hypersensitivity reactions and drug fever may occur.

Common (may affect up to 1 of 10 patients treated):
- Headache;
- Dizziness;*
- Diarrhoea;
- Abdominal pain;
- Nausea;
- Vomiting;
- Rash;
- Flatulence.

* Considered as a rare side effect in PENTASA® 1 g tablets

Rare (may affect up to 1 of 1,000 patients treated):
- Inflammation of heart muscle or heart sac (myocarditis, pericarditis) which can cause shortness of breath and chest pain or palpitations (rapid or irregular heartbeats);
- Inflammation of the pancreas (pancreatitis) including symptoms like back and stomach pain;
- Increased amylase (enzyme that helps digest carbohydrates);
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

Very rare (may affect up to 1 of 10,000 patients treated):
- Anaemia and other blood disorders (decrease in the numbers of certain blood cells, which can cause unexplained bleeding, bruising, fever or sore throat);
- Hypersensitivity reactions such as allergic exanthema;
- Severe diarrhoea and abdominal pain because of an allergic reaction to this medicine within the bowel;
- A condition affecting the nerves of the hands and feet, symptoms include tingling and numbness (peripheral neuropathy);
- Accumulation of fluid in the heart sac (pericardial effusion) which can cause chest pain or pressure;
- Allergic reactions and increase of connective tissue (fibrosis) in the lung, inflammation of the lining of the lungs or lung scarring (symptoms include coughing, bronchial cramps (bronchospasm), chest discomfort or pain on breathing, breathing difficulties, bloody and/or excessive phlegm);
- Pancolitis (a kind of inflammatory bowel disorder (IBD) that affects the entire internal lining of the large bowel);
- Liver disorders (symptoms include jaundice (yellowing of the skin or eyes) and/or pale bowel motions);
- Reversible hair loss;
- Muscle or joint pain;
- Inflammation which can affect different parts of the body such as joints, skin, kidneys, heart etc. (symptoms include painful joints, fatigue, fever, abnormal or unexplained bleeding (e.g. nose bleeds), bruising, purple discoloration of the skin (including severe skin erosions and severe blistering that may affect the skin as the protective barrier of the body));
- Kidney disorders (symptoms include blood in the urine and/or swelling due to build up of fluid);
- Change in urine colour;
- Semen with a low concentration of sperm (oligospermia) (reversible);
- Allergic reactions and fever may occasionally occur.

Not known (frequency cannot be estimated from the available data)
- kidney stones and associated kidney pain (see also section 2)

There have been very few reports of benign intracranial hypertension in adolescents. Symptoms include headache, nausea, vomiting or visual and/or hearing disturbances.

Some of these side effects may be caused by the bowel disease itself.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store PENTASA® prolonged release tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not freeze. Store in the original package in order to protect from light.

Never throw away any medicines via wastewater (e.g. not via toilet or sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What PENTASA® prolonged release tablets contain
Active ingredient:
PENTASA® 1g prolonged release tablets: each prolonged release tablet contains 1g Mesalazine.
PENTASA® 500mg prolonged release tablets: each prolonged release tablet contains 500mg Mesalazine.
The other ingredients are: Povidone K30, ethyl cellulose, magnesium stearate (Ph. Eur.), talc, microcrystalline cellulose.

What PENTASA® prolonged release tablets look like and contents of the pack
PENTASA® 1g prolonged release tablets:

Light grey to light brown, spotted, oval tablet. Stamped on both sides: *PENTASA*. Packs with 60 (6 x 10) prolonged release tablets and 150 (15 x 10) prolonged release tablets.

PENTASA® 500mg prolonged release tablets:

White-grey to pale brown, specked, round tablets, scored and marked *PENTASA* on one side and *500 mg* on the other side. Pack with 100 or 300 prolonged release tablets.
Not all pack sizes are marketed.

Prescription condition: prescription only.
List II.

Marketing Authorisation Holder: Ferring GmbH, Wittland 11, 24109 Kiel, Germany.
Marketing Authorisation Holder in Morocco: SOTHEMA, B.P. N° 1 - 27182 Bouskoura, Morocco.
Manufacturing Site, Primary and Secondary Packaging Site: Ferring International Center SA, Chemin de le Vergognausaz 50, 1162 St-Prex, Switzerland.
Batch Releasing Site:
Middle East & Anglophone Africa: Ferring International Center SA, Chemin de le Vergognausaz 50, 1162 St-Prex, Switzerland.
Maghreb Region & Francophone Africa: Ferring GmbH, Wittland 11, 24109 Kiel, Germany.

Registration number in Algeria for PENTASA® 1g prolonged release tablets:
Registration number in Algeria for PENTASA® 500mg prolonged release tablets: 15/03/10 N 075/275

Registration number for PENTASA® 1g prolonged release tablets in Morocco: N 115/20 DMP/21/ NNPd
Registration number for PENTASA® 500mg prolonged release tablets in Morocco: 546/18 DMP / 21 / NCCD

Registration number for PENTASA® 1g prolonged release tablets in Tunisia: 55230211
Registration number for PENTASA® 500mg prolonged release tablets in Tunisia: 5523024

This leaflet was last revised in January 2021.

This is a Medicine
- A medicine is a product, which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period or treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep the medicine out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

To Report Side Effects
Kingdom of Saudi Arabia
The National Pharmacovigilance (NPC)
- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website**:** https://ade.sfda.gov.sa/